Nos. 02-1845 & 03-83

In the Supreme Court of the United States

AETNA HEALTH INC.,
Petitioner,

v.

JUAN DAVILA
Respondent.

CIGNA HEALTHCARE OF TEXAS, INC.
Petitioner,

v.

RUBY R. CALAD, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF TEXAS, CALIFORNIA, CONNECTICUT, DELAWARE, ILLINOIS, KANSAS, LOUISIANA, MARYLAND, MINNESOTA, MISSOURI, MONTANA, NEVADA, NEW MEXICO, NEW YORK, OHIO, OKLAHOMA, OREGON, PUERTO RICO, UTAH, VERMONT, WASHINGTON AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

The Texas Health Care Liability Act creates a tort cause of action against an HMO that negligently renders a medical decision that affects the quality of a patient's treatment and results in injury to the patient. ERISA §502(a) provides a set of civil-enforcement remedies whereby ERISA plan participants can obtain plan benefits or otherwise enforce their contractual rights under ERISA plans. In enacting §502(a), did Congress clearly and manifestly intend to displace state-law tort claims for HMOs' negligent medical decisions with such preemptive force as to transform those claims into federal actions under ERISA removable to federal court?

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INTEREST OF *AMICI*

The State *amici curiae*, through their Attorneys General, respectfully submit this brief in support of Respondents. States have a vital interest in protecting their power to regulate traditional areas of state concern, such as the health and safety of their citizens. Nothing in the Employee Retirement Income Security Act of 1974 (ERISA) evidences an intent to eliminate the States' role in regulating health care. *N.Y. State Conference of Blue Cross & Blue Shield v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995). Thus, the States have an interest in ensuring that ERISA's preemption provisions are not construed more broadly than Congress intended.

Texas Health Care Liability Act §88.002(a) directly serves the State's interest in protecting the health and safety of its citizens. It provides a cause of action against a health maintenance organization (HMO) that breaches its duty to exercise ordinary care when making health care decisions that affect the quality of a patient's treatment. The State, in its role as regulator of health care, has determined that when an HMO assumes responsibility for making medical-necessity decisions involving the exercise of medical judgment, and that direction results in personal injury, the HMO should be held responsible for its erroneous medical judgment. Following Texas's lead, nine other States have passed managed care liability laws, others have passed some form of consumer protection from HMO actions, and an increasing number of state legislatures have contemplated new liability legislation.

The HMO-petitioners in this case claim that their allegedly negligent medical decisions can be redressed only through the contractual remedies provided in ERISA §502(a). If this contention is correct, then HMOs enjoy immunity from any harm proximately resulting from their medical negligence by virtue of a statute that was not designed to regulate health care providers. The State *amici curiae* ask the Court to hold that Congress did not clearly and manifestly intend that §502(a)'s remedies would completely preempt States' traditional role in regulating health care quality standards.

SUMMARY OF THE ARGUMENT

Protecting the health and safety of her citizens is the principal obligation of each and every state government. For this reason, regulating health care has long been a traditional area of state concern, manifested in statutory and common law safeguards against negligent and harmful medical care.

Congress, in enacting the Employee Retirement Income Security Act of 1974 (ERISA), did nothing to change that.

Modern HMO practice, unforseen in 1974, has resulted in managed care providers routinely making medical judgments and decisions. As this Court explained in *Pegram v. Herdrich*, 530 U.S. 211, 228 (2000), HMO "medical necessity" determinations implicate both "eligibility" and "treatment," and the two "are often practically inextricable from one another." And the result of these mixed "medical necessity" decisions often dictates the course and quality of a patient's health care.

Responding to the need to ensure that patients are protected from negligent and wrongful conduct by HMOs, Texas and nine other States have adopted some form of HMO-liability statute. These statutes do not seek to mandate the specific terms of particular HMO plans, but rather to bring day-to-day HMO medical treatment determinations back into the ambit of ordinary standards of care. In this case, the Texas Health Care Liability Act provides such scrutiny, within a state framework that entitles HMOs to significant procedural protections, including in many circumstances requiring independent review before suit may be brought.

When insurance companies act as medical professionals, and make medical judgments, these States have determined that they should be subject to medical standards of care. Aetna and CIGNA urge this Court to read ERISA §502(a) to insulate them from any legal scrutiny, so that negligent or wrongful medical decisions by HMOs would be immune from liability.

ERISA provides no basis to do so. In urging complete preemption under §502(a), Petitioners face an extremely high threshold: this Court has "worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act *unless that was the clear and manifest purpose of Congress*." *N.Y. State Conference of Blue Cross & Blue Shield v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (internal quotation and citation omitted) (emphasis added).

Petitioners have presented no compelling argument that Congress had a "clear and manifest purpose" to completely preempt state health care liability for HMOs making medical judgments. Congress did not anticipate modern HMO practice, much less clearly intend to create a "'regulatory vacuum,' in which it displaced state-law regulation of welfare benefit plans while providing no federal substitute." *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 467 (CA3 2003) (Becker, J., concurring).

Were Aetna and CIGNA to prevail, patients would be left with no meaningful remedy for negligent and wrongful medical decisions made by HMOs. ERISA would not provide relief, and the health care laws of sovereign States would be completely preempted from providing those protections. This Court's precedents do not compel such an outcome, nor does any "clear and manifest" intent of Congress.

ARGUMENT

I. THE TEXAS HEALTH CARE LIABILITY ACT (THCLA), PROVIDES A TORT CAUSE OF ACTION FOR PATIENTS INJURED BY AN HMO'S NEGLIGENT MEDICAL DECISIONS THAT AFFECT THE QUALITY OF TREATMENT.

A. In Making Mixed Eligibility and Treatment Decisions, HMOs Exercise Professional Medical Judgment That Affects the Quality of Treatment.

Managed care providers, including HMOs, perform two distinct functions: (1) the preparation and administration of benefits plans and (2) the provision of medical treatment to plan beneficiaries. Some HMOs employ doctors and provide medical services directly; others contract with a network of doctors to provide medical services based on a single reimbursement plan. In either case, when HMOs make a decision whether to cover a particular patient's medical care, they blend these two roles, making what this Court has called a "mixed" determination of both "eligibility" and "treatment." *See generally Pegram v. Herdrich*, 530 U.S. 211, 229 (2000). That is, every time an HMO determines whether a particular medical treatment is "medically necessary," and therefore covered by the benefit plan, it exercises some degree of medical judgment, albeit mixed with questions of plan administration. *See, e.g.*, *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 453 (CA3 2003). Because HMOs make this determination prior to or at the point of treatment, they can and do affect the quality of medical treatment afforded plan beneficiaries.

1. Any "medical necessity" determination necessarily involves medical judgment.

The Court has recognized that HMO "medical necessity" determinations, though made in the course of assessing coverage under ERISA-qualified health plans, involve an element of professional medical judgment that bears on treatment. In *Pegram v. Herdrich*, the Court addressed the nature of these determinations in considering whether an HMO-employed doctor acted as a fiduciary for ERISA purposes in providing medical services under an ERISA-qualified plan. *Pegram*, 530 U.S., at 215. In aid of its analysis, the Court initially identified two categories of "arguably administrative" acts by HMOs: (1) "Pure eligibility decisions," which "turn on the plan's coverage of a particular condition or medical procedure for its treatment;" and (2) "Treatment decisions," which are "choices about how to go about diagnosing and treating a patient's condition: given a patient's constellation of symptoms, what is the appropriate medical response?" *Id.*, at 228.

The Court concluded that HMOs' "medical necessity" determinations implicated both "eligibility" and "treatment":

> "These decisions are often practically inextricable from one another . . . . This is so not merely because, under a scheme like [Petitioners'], treatment and eligibility decisions are made by the same person, the treating physician. It is so because a great many and possibly most coverage questions are not simple yes-or-no questions . . . . The more common coverage question is a when-and-how question. . . . The issue may be, say, whether one treatment option is so superior to another under the circumstances, and needed so promptly, that a decision to proceed with it would meet the medical necessity requirement that conditions the HMO's obligation to provide or pay for that particular procedure at that time in that case." *Id.*, at 228-29.

Thus, the mere fact that the HMO in *Pegram* had made "medical necessity" a condition of coverage did not render that inquiry a contractual question of eligibility under the plan or ERISA. Quite the contrary, the treatment aspect of the decision removed the "medical necessity" determination from the ambit of ERISA fiduciary obligations altogether. *Id.*, at 237. Instead, the Court indicated that these sort of decisions implicated state medical malpractice law, *see id.*, at 235-37, which generally provides standards of care and liability schemes governing health-care professionals.

Moreover, the Court made clear that the "mixed" nature of the "medical necessity" determination did not turn on the fact that the HMO provided medical services through physicians it employed. *Id.*, at 228 (noting that decision is mixed "not merely" because HMO-employed physician made both treatment and eligibility decisions). In the Court's example, it observed that these "mixed" decisions are involved in whether the HMO will "provide *or pay*" for a particular procedure at a particular time. *Id.*, at 229. In other words, a third-party network-HMO whose ultimate role may be only to pay or not to pay for treatment still engages in a mixed decision involving treatment questions. It is the *nature* of "medical necessity" determinations—the "when-and-how" questions—and not who makes them that renders them in part an exercise of medical judgment that is traditionally subject to state regulatory control. *See id.*, at 228-29.

2. In making "medical necessity" determinations, HMOs can and do dictate the quality of a patient's treatment.

Unlike the processing of claims for most categories of ERISA benefits, such as pension, disability, and death benefits, HMOs make eligibility decisions *before* the events giving rise to benefit claims—*i.e.*, either prior to or at the point of medical treatment. This arrangement creates a window between diagnosis and treatment

in which the HMO's "medical necessity" determinations can affect the quality of treatment the patient receives, with potentially harmful or even fatal consequences. Davila's and Calad's cases both demonstrate how this can occur.

a. Medical-necessity judgments made by HMOs in structuring benefit plans and in applying utilization review dictate medical treatment.

HMOs engage in *ex ante* medical-necessity judgments in drafting their own plan requirements. The HMOs develop and market packaged benefits arrangements, which offer varying levels of coverage for varying prices per covered beneficiary. This package is marketed, not to the beneficiaries directly but to the ERISA-plan established by the beneficiaries' employer. Although HMOs have the right to draft treatment plans that do not cover particular treatments, when an HMO chooses to provide coverage for a range of treatments, or to mandate a set of pre-certification requirements for particular treatments, it makes an inherent medical judgment that can dictate the course of treatment.

In this regard, the HMO makes judgments that various treatments are sufficiently equivalent that one can be replaced with the other, or that the patient *must* attempt a less expensive treatment before the HMO will consider covering a more expensive option for the same illness. These determinations involve a medical assessment of the health risks and benefits of favoring one treatment over another. In addition, questions of effectiveness and the possibility of side effects are essential to drawing up such multi-tiered coverage options. By indicating that certain treatments are equivalents, or that a patient must follow a certain course of treatment before other options will be covered, the HMO interjects itself into the treatment decision-making process.

HMOs' medical-necessity decisions also dictate treatment through the "utilization review" process, by which the HMO determines payment-eligibility *before* a medical professional actually provides treatment. When an HMO reviews a patient's treatment based on that patient's individual condition to determine what treatment is "medically necessary," it mirrors exactly the decision made by the treating physician. The only difference is that the HMO characterizes its decision as interpretation of a contract, while the doctor, by virtue of a state-issued medical license, is subject to a professional standard of care designed to protect patient safety. In practice, however, this is a distinction without a difference.

Although the terms of the HMO agreements make clear that medical professionals are not *prevented* from providing care that the HMO determines is not "medically necessary," the assumption that these contractual agreements do not impact medical treatment decisions ignores the inability of most HMO beneficiaries to pay for critical procedures out-of-pocket:

> "[I]n many cases, participants must take HMOs' decisions as law—for example, when Aetna's utilization review board denied coverage for DiFelice's specialized tracheostomy tube, he faced the decision whether to pay for the specialized tube out-of-pocket, whereas appealing the HMO's decision was simply impractical in the face of a medical emergency. In such cases, the critical insight is that the HMO *de facto* determines a patient's *actual treatment* along with his eligibility for benefits, for it will be a relatively rare person who is able to pay for invasive procedures out-of-pocket." *DiFelice*, 346 F.3d, at 464 (Becker, J. concurring).

In such situations, even a small difference in the quantum of care provided can make the difference between a patient who survives an emergency and one who does not. Therefore, contrary to CIGNA's assertions, *see* CIGNA Br., at 28, the difference between payment decisions made before and after treatment does affect the treatment

and health of the patient-beneficiary. It can be the difference between life and death.

b. In these cases, the HMOs' medical-necessity determinations dictated Davila's and Calad's treatment.

Davila's and Calad's cases represent two instances in which their HMOs' medical-necessity determinations allegedly dictated the course of their treatment.[1] Davila's doctor proscribed a drug called Vioxx to treat his arthritis pain and sought pre-certification for the prescription from Aetna. Pet. App. 77a. Aetna's pharmacologist advised Davila's doctor that the Aetna plan would cover Vioxx "only if the member has already tried—or cannot try, because of allergy or contraindication—at least two of the fifteen other, *similar* drugs that are listed on the formulary." Aetna Br., at 9 (emphasis added). In so doing, Aetna had already made the medical determination that the other drugs on the formulary were "similar" to Vioxx and that it would be acceptable for a patient to use those drugs unless he had a known allergy or contraindication. Necessarily, Aetna dictated that a patient was *required* to use two of those drugs—and that those treatments would have to fail—as a precondition to providing coverage for Vioxx. Again, Aetna had made the medical determination that, absent a known allergy or contraindication, the use and failure of two of these drugs was an acceptable risk for a patient to endure as part of its formulary program.

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1. The *Amici* States express no opinion as to the truth of the allegations in Davila's and Calad's complaints. This brief assumes the truth of those allegations—that the HMOs' medical decisions were in fact negligent—only for purposes of assessing federal-question jurisdiction under the well-pleaded complaint rule. *See Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 9-12 (1983).

Aetna points out that Davila failed to exercise certain remedies available to him when it denied coverage for Vioxx: (1) filing a grievance with Aetna, (2) appealing Aetna's decision to an Independent Review Organization (IRO), or (3) filing a lawsuit under ERISA §501(a)(1)(B) to compel payment. Aetna Br., at 9. Of course, none of these options addresses how Davila could treat his arthritis pain while he pursued these remedies; as Aetna admits, the grievance and IRO procedures could be expedited only if Davila's condition were life-threatening. *Id.* Thus, at that time, Davila's treatment options were: (1) continue to suffer arthritis pain; (2) find a way to pay for the Vioxx prescription himself, if possible; or (3) use another drug to relieve his pain. In practice, Davila's available course of medical treatment was to try another drug, and naturally, his doctor chose one that Aetna directed he try as a precondition to coverage for Vioxx: Naprosyn. *See* Pet. App. at 68a.

Apparently, Davila's use of this drug adhered precisely to the dictates of Aetna's plan. He had no known contraindication or allergy with respect to Naprosyn. He tried the drug and it failed, leaving him with one more drug treatment to attempt and fail before Aetna would considering covering the medication his doctor originally prescribed. But the consequences were devastating: as a result of Aetna's mandated administration of an alternate drug, Naprosyn, Davila was hospitalized and diagnosed with bleeding ulcers. Pet. App. 68a. In this way, through its medical-necessity determinations, Aetna affected the quality of the *immediate* treatment for Davila's arthritis—regardless of whether he initiated a grievance, appeal, or ERISA remedy—and that treatment resulted in concrete harm.

Similarly, Calad entered the hospital for a hysterectomy with reconstructive surgery, and her doctor determined that she needed to stay in the hospital for more than twenty-four hours. CIGNA Br., at 3. CIGNA's utilization review organization—staffed by nurses and consulting physicians—determined that hospitalization beyond

twenty-four hours was not "medically necessary," and therefore, not covered under the CIGNA plan. *Id.*, at 3-4. In other words, CIGNA engaged in precisely the same medical evaluation as Calad's doctors had done, but reached a different medical judgment.

Like Aetna, CIGNA points out that Calad did not file a grievance or an appeal to an IRO to review CIGNA's determination. *Id.*, at 4. Again, however, those options failed to address how Calad could continue to receive treatment once her hospital stay extended beyond twenty-four hours. Thus, Calad's treatment options in the twenty-fifth hour were: (1) return home against the advice of her treating physician; or (2) pay for the hospitalization out-of-pocket. Calad was unable to pay for the additional hospital stay herself, so her only "treatment" alternative was to return home. *Id.*, at 4. Calad developed medical complications within a few days. *Id.* In this manner, CIGNA's medical-necessity determination dictated the immediate course of Calad's treatment once she had been in the hospital for twenty-four hours.

B. Texas and Nine Other States Regulate HMOs in Making Medical-Necessity Determinations That Affect the Quality of Treatment Available Under Their Health Plans.

Texas and nine other States have now adopted some form of HMO-liability statute[2] to address the fact that HMOs exercise

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2. Ten States have passed managed care liability laws: Arizona, California, Georgia, Louisiana, Maine, New Jersey, Oklahoma, Texas, Washington, and West Virginia. *See* ARIZ. REV. STAT. §20-3153; CAL. CIV. CODE §3428; GA. CODE ANN. §51-1-48; LA. REV. STAT. §22:3085; ME. REV. STAT. tit. 24-A, §4313; N.J. STAT. 2A:53A-33; OKLA. STAT. tit. 36, §6593; TEX. CIV. PRAC. & REM. CODE §88.002; WASH. REV. CODE ANN. §48.43.545; W. VA. CODE ANN. §33-25C-7. Other States may impose similar liability schemes through their common law. The National Conference of State Legislatures maintains a website containing

medical judgment in the same manner as doctors and nurses, and those judgments can and do affect the quality of patients' treatment, with potentially harmful consequences. Such legislation clearly falls within the States' traditional province of regulating medical care for the health and safety of their citizens.

The Texas statute, the Texas Health Care Liability Act (THCLA), generally imposes a duty on HMOs and other managed care entities to exercise ordinary care in making medical determinations at the point of treatment that affect the quality of treatment. TEX. CIV. PRAC. & REM. CODE §§88.001(4), .002(a). And it creates a cause of action when the HMO fails to exercise such care and thereby proximately causes injury to a patient. *Id.*, §88.002(a), (b). Thus, contrary to Aetna's and CIGNA's contentions, the THCLA does not simply create a tort for the denial of benefits. Instead, it is carefully crafted to address situations such as Davila's and Calad's—where the HMO negligently exercises medical judgment during the treatment window in which the claims review process could not have been completed.

1. In most circumstances, the THCLA requires HMOs to submit to an independent review procedure.

Texas managed care beneficiaries, as a general matter, do not have the right to bring suit against their managed care entities. They must first either (1) exhaust the appeals and review provisions of their health care plan or (2) submit their claims for review by an independent review organization if the managed care entity participates in such a program. TEX. CIV. PRAC. & REM CODE §88.003(a), (c); *see also Corporate Health Ins. v. Tex. Dep't of Ins.*, 215 F.3d 526 (CA5 2000), *rev'd in part, remanded sub nom. Montemayor v. Corporate Health Ins.*, 536 U.S. 935 (2002), *opinion*

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current and pending legislation at www.ncsl.org/programs/health/liable.htm (last visited January 9, 2004).

modified and reinstated, 314 F.3d 784 (relying on *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002)). In its first few years, this independent review process has dealt with successively greater numbers of challenges to HMO eligibility determinations, and has thus helped to ensure proper provision of care. *See* www.ama-assn.org/amednews/2001//05/28/gvsa0528 .htm (last visited January 12, 2004).

However, if a plan beneficiary can demonstrate that (1) harm has already occurred because of the HMO's actions and (2) the independent review process would not be beneficial, the beneficiary may bring suit directly against the managed care entity. TEX. CIV. PRAC. & REM. CODE §88.003(f).[3] Thus, Texas law does not expose HMOs to potential liability for their medical decisions until a patient-beneficiary has already been harmed by an HMO's act or omission. And it does so only when the HMO's decision has harmed a beneficiary before the applicable appeals and independent review process can be completed.

2. To complement the independent review process, the THCLA imposes a duty on HMOs making "health care treatment" decisions but does not create an obligation to provide coverage not described in the HMO plan.

HMOs are subject to voluntary participation in Texas's independent review process. However, as explained *supra*, in some cases the harm caused by the HMO occurs before the review process can be completed. To fill this gap, the THCLA imposes a duty of ordinary care on managed care entities that make medical decisions.

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3. Section 88.003(f) renders irrelevant the fact that Calad and Davila did not complete the HMO's internal appeals processes or apply for independent review of their cases. TEX. CIV. PRAC. & REM. CODE. 88.003(f).

TEX. CIV. PRAC. & REM. CODE §§88.002(a), .003(f). It also creates vicarious liability for torts committed by an HMO's agents and ostensible agents or "representatives who are acting on its behalf and over whom it has the right to exercise influence or control or has actually exercised influence or control which result in the failure to exercise ordinary care." *Id.*, §88.002(b). Thus, the THCLA imposes a duty of ordinary professional care on an HMO to the extent that its actions harm a patient based on the predetermination of benefits without exercising an adequate level of care.

Aetna and CIGNA erroneously assert that all Davila or Calad need do to recover under the THCLA is establish that the treatment they were denied was actually covered by their respective plans. Aetna Br., at 18; CIGNA Br., at 11; *see also* U.S. Br., at 20. In this regard, they assume that the only source of a duty involved in Davila's and Calad's claims was the terms of the plan. The THCLA, however, imposes liability for failure to follow professional standards of ordinary care, not for failure to fulfill the benefit-plan agreement.[4]

Likewise, the United States mistakenly urges that the THCLA only creates an additional remedy for the HMO's failure to provide a plan benefit, and so a plaintiff need only establish that a particular treatment was covered by the plan in order to be entitled to relief. *See* U.S. Br., at 20-21. If Texas law functioned in this manner, it would effectively establish a minimum coverage requirement under state law, imposing liability on HMOs for designing plans that provide less care than the prevailing professional standard. But the

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4. This conclusion is underscored by the fact that the THCLA creates remedies only for injury that occurs before plan payment. *See* TEX. CIV. PRAC. & REM. CODE §§88.001(5), .002 (imposing liability only for decisions made "when medical services are actually provided"). This limitation prevents the law from applying to "pure eligibility" decisions. *See* discussion *supra*, Part I.A.1.

plain text of the THCLA *prevents* this outcome, by establishing that the provision will not be read to impose an obligation to cover treatment that is not covered by the agreed health plan. TEX. CIV. PRAC. & REM. CODE §88.002(d). The THCLA does not operate to create substantive standards for HMO health care benefits. It does not punish HMOs for excluding coverage for particular treatments or illnesses. Instead, the THCLA imposes a duty of care in establishing the available treatment options under HMO plans and ensures that HMOs administer those plans consistent with sound medical judgment, within the terms of the HMO agreement.

In sum, the THCLA contemplates that HMOs' medical-necessity determinations will be evaluated to determine whether they comport with professional standards of ordinary care, not whether they adhered to the terms of the plan. The operative question is not whether the treatment at issue was within the plan's coverage, but whether the HMO acted in a manner consistent with professional norms of conduct for a reasonably prudent HMO.[5]

The difference in the source of the obligation makes a difference in the remedy asserted. The tort remedy created by the THCLA compliments the state-law independent review process by creating

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5. Under Texas law, the scope of professional duty must be established on the basis of expert testimony regarding the appropriate standard of care to be used in similar circumstances. *Rehabilitative Care Sys. of Am. v. Davis*, 73 S.W.3d 233, 233 (Tex. 2002); *Bowles v. Bourdon*, 219 S.W.2d 779, 782 (Tex. 1949). Therefore, under the THCLA, the applicable standard of care would be that of a similarly situated medical care institution making a similar determination, not the standard for an individual medical professional. *See Birchfield v. Texarkana Mem'l Hosp.*, 747 S.W.2d 361, 366 (Tex. 1987). Aetna and CIGNA would therefore be held to the standard of care for an HMO, not for an individual doctor, and that standard will presumably account for the circumstance that they are providing medical care in the context of creating and administering a cost-controlled medical benefits program.

a coordinate duty to the ERISA obligation to administer the plan as a fiduciary. While the independent review procedure helps to ensure that claims are fairly resolved, the tort remedy serves to promote careful medical decision-making. These are different goals, reached by different means.

The independent review process has continued to expand, and has effectively reversed or adjusted many HMO benefits determinations. The tort remedy, however, has not been widely used. Indeed, the only two jury verdicts so far rendered under the THCLA resulted in one jury award of punitive damages and one exoneration. Mark A. Hall & Gail Agrawal, *The Impact of State Managed Care Liability Statutes*, HEALTH AFFAIRS, Sept./Oct. 2003, at 138, 141. This scant use of the statute refutes Aetna's and CIGNA's warnings that the THCLA and laws like it will ruin HMOs by imposing liability whenever patients are unsuccessfully treated under HMO-provided medical benefit plans.

II. CONGRESS DID NOT CLEARLY AND MANIFESTLY INTEND TO DISPLACE STATE TORT LAWS LIKE THE THCLA WITH SUCH PREEMPTIVE FORCE AS TO TRANSFORM THEM INTO FEDERAL ACTIONS UNDER ERISA.

Davila's and Calad's THCLA claims do not target eligibility determinations under their respective health plans, but the negligent exercise of medical judgment by their HMOs that affected the quality of their immediate medical treatment. Davila and Calad do not seek redress for the improper processing of benefits claims, or to enforce rights guaranteed them by ERISA, but to recover damages for personal injuries proximately caused by their HMOs' negligent medical judgment and the resulting impairment of their medical treatment. The question presented in this case is whether Congress, in establishing a scheme of civil-enforcement remedies in ERISA §502(a), intended to displace state-law claims of this nature with such preemptive force as to transform them into federal actions

under ERISA, thereby permitting their removal to federal court. *See Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987).

Because the state law in question regulates health care, a subject of traditional state regulation, Aetna and CIGNA have a significantly elevated burden to demonstrate the requisite congressional intent to preempt—they must show that preemption was "the clear and manifest purpose of Congress." *See infra*, Part II.A. But they have failed to direct the Court to any such clear and manifest congressional intent. Davila's and Calad's state-law claims do not fall within the contours of congressionally mandated preemption as it has been defined by the Court. *See infra*, Part II.B. Furthermore, Aetna and CIGNA have not shown that Congress clearly and manifestly intended for those contours to extend to the area of core State powers implicated by Davila's and Calad's claims. *See infra*, Part II.C.

A. Aetna and CIGNA Must Show That Congress Clearly and Manifestly Intended To Completely Preempt State-Law Health-Care Liability Claims.

As discussed in Part I, the THCLA regulates the provision of health care in the State of Texas by (1) imposing a duty on HMOs to exercise ordinary care in making medical decisions at the point of treatment that will affect the quality of that treatment, and (2) creating a cause of action against an HMO for harm that results from its breach of this duty. *See supra*, Part I. Health-care regulation of this sort is within "the historic police powers of the State." *See De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997); *see also N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995) (noting that "general health care regulation . . . historically has been a matter of local concern").

The localized nature of health care regulation substantially raises the bar for a federal statute to preempt state law in this area. The

Court has "never assumed lightly that Congress has derogated state regulation, but instead [has] addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law." *Travelers*, 514 U.S., at 654. And, "where federal law is said to bar state action in fields of traditional state regulation, . . . [the Court has] worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act *unless that was the clear and manifest purpose of Congress*." *Id.*, at 655 (internal quotation and citation omitted) (emphasis added); *see also Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997).[6]

Consequently, "in the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of congressional purpose." *Pegram v. Herdich*, 530 U.S. 211, 237 (2000).[7] Overcoming the presumption of no

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6. Aetna contends that *Travelers*, *Dillingham*, and *De Buono* are inapposite because those cases concerned defensive preemption under ERISA §514(a) rather than complete preemption under §502(a). *See* Aetna Br., at 37-40. But there is no principled reason why these decisions' general description of the preemption threshold would apply to one form of preemption and not the other. Indeed, it would make little sense to require a more substantial showing of congressional intent for §514(a) preemption—which merely provides an affirmative defense—than for §502(a) preemption—which displaces state law to such a degree that it transforms a civil action invoking that state law into a federal question. *See infra*, Part II.B. If anything, the more intrusive effect occasioned on state law by §502(a) complete preemption logically demands a greater showing of congressional purpose.

7. CIGNA protests that this precedent does not suggest "the existence of some unspoken health-care exemption from §502(a)'s preemptive force." CIGNA Br., at 7. The *Amici* States do not urge such a *per se* rule. What is plain from the Court's precedent, however, is that any preemption of state health-care regulation must rest on a heightened

preemption and establishing the requisite clear and manifest congressional intent is a "considerable burden." *De Buono*, 520 U.S., at 814. Aetna and CIGNA have failed to meet that burden here. They have not shown that the Court's prior explications of Congress's preemption objective control the preemption question in this case. And they have not otherwise demonstrated that Congress clearly and manifestly intended to preempt state health regulation of this sort when HMOs incorporate medical decision-making into their coverage determinations that affects the quality of a patient's treatment.

B. Davila's and Calad's Claims Do Not Fall Within the Existing Contours of §502(a) Complete Preemption as Defined by the Court.

The Court has held that Congress intended ERISA §502(a) to completely preempt a state-law cause of action on only three occasions: *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987); *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987); and *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990). In both *Pilot Life* and *Metropolitan Life*, the Court held that §502(a) preempted state-law tort claims arising out of the improper processing of ERISA benefit claims in violation of a duty of good faith imposed generally on contracting parties. And in *Ingersoll-Rand*, the Court concluded that §502(a) preempted state-law tort claims designed to vindicate rights already expressly guaranteed by ERISA. Davila's and Calad's state-law claims do not fall within the contours of congressionally mandated preemption as it has been defined in these cases.

1. *Pilot Life*

In *Pilot Life*, the plaintiff-employee filed an action against the insurer/administrator of his employer's disability benefits plan

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showing of "clear and manifest" congressional intent. *Pegram*, 530 U.S., at 237.

arising out of the insurer's "failure to provide benefits under the insurance policy." 481 U.S., at 43. The employee's complaint contained several state-law claims seeking compensatory and punitive damages, but the only claim at issue on appeal was the cause of action for "tortious breach of contract." *Id.*, at 48. This action was in the nature of a bad-faith claim—*i.e.*, "the breach of contract was 'attended by some intentional wrong, insult abuse, or gross negligence'" or was otherwise "'arbitrary.'" *Id.*, at 49, 50 (quoting *Am. Ry. Express Co. v. Bailey*, 107 So. 761, 763 (Miss.1926) and *Blue Cross & Blue Shield of Miss., Inc. v. Campbell*, 466 So. 2d 833, 842 (Miss. 1984)).

The dispute did not concern whether this claim could be removed to federal court; the employee had filed his suit as a diversity action in federal district court under 28 U.S.C. §1332. *Id.*, at 43-44. Rather, the sole issue before the Court was whether the insurer was entitled to summary judgment on the employee's "tortious breach of contract" claim based on the defense that the claim was preempted under ERISA §514(a)'s express preemption provision. *Id.*, at 48. In aid of its §514(a) preemption analysis, the Court noted that it should seek guidance in the object and policy of ERISA as a whole. *Id.*, at 51. And specifically, because the employee's "tortious breach of contract" claim sought "remedies for the improper processing of a claim for benefits under an ERISA-regulated plan," the Court felt compelled to examine Congress's intent in enacting a scheme of civil-enforcement remedies in ERISA §502(a). *Id.*, at 51-52.

The Court concluded that Congress intended the civil-enforcement provisions of §502(a) to be "the exclusive vehicle for actions by ERISA-plan participants and beneficiaries asserting improper processing of a claim for benefits." *Id.*, at 52. In support of this conclusion, the Court reasoned that the detail and comprehensiveness of §502(a) reflected careful consideration by Congress of which remedies for improper "claims settlement" would

be allowed, and necessarily, which would not. *See id.*, at 52-54. The Court found confirmation of this intent in ERISA's legislative history—the Conference Report expressly invoked the complete preemption afforded by §301 of the Labor-Management Relations Act as a model for ERISA:

> "[W]ith respect to suits to enforce benefit rights under the plan or to recover benefits under the plan which do not involve application of the Title I provisions, they may be brought not only in U.S. district courts but also in State courts of competent jurisdiction. All such actions in Federal or State courts are to be regarded as arising under the laws of the United States in similar fashion to those brought under section 301 of the Labor-Management Relations Act of 1947." H.R. CONF. REP. NO. 93-1280, at 327 (1974), *reprinted in* 1974 U.S.C.C.A.N. 4639, 5107, *and quoted in Pilot Life*, 481 U.S., at 55.

This explicit reference to the LMRA was significant because §301 "displace[s] entirely any state cause of action 'for violation of contracts between an employer and a labor organization.' Any such suit is purely a creature of federal law . . . ." *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 23 (1983) (quoting Labor Management Relations Act §301(a), 29 U.S.C. §185(a)).

Therefore, *Pilot Life* held that Congress intended for §502(a) to displace state-law actions "asserting improper processing of claims under ERISA-regulated plans" with such force that they "be treated as federal questions." 481 U.S., at 56. A state-law claim for "tortious breach of contract" grounded in a general duty to contract in good faith was therefore completely preempted. *Id.*, at 49-51.

Pilot Life does not mandate complete preemption of Davila's and Calad's THCLA claims for two reasons. First, as discussed in Part I, Davila's and Calad's suits are not directed to the "improper

processing of benefits claims." That is, they do not seek redress for the denial of benefits or improper conduct in the processing of benefits claims. Rather, they seek a remedy for their HMOs' negligent exercise of medical judgment at the point of treatment that adversely affected the quality of their treatment and resulted in personal injury. Their malpractice actions are not transformed into "improper processing" claims simply because the HMOs made their negligent medical decisions in the course of evaluating coverage. *See Land v. CIGNA Healthcare of Fla.*, 339 F.3d 1286, 1293 n.5 (CA11 2003) (holding that *Pilot Life* does not control preemption of "malpractice action" which is not "based solely upon the improper processing of a claim").

Second, *Pilot Life* is inapposite on its facts—it holds only that §502(a)'s comprehensive remedial scheme for claims under ERISA plans displaces state-law torts arising from a general duty to perform contracts in good faith. To be sure, in providing an array of remedies for breaching ERISA plan provisions, Congress may not have directly contemplated that the *manner* in which the plan was breached would also be redressable outside of ERISA. But that logic cannot be stretched to suggest that Congress therefore clearly and manifestly intended to displace state-law torts arising from a specific duty to exercise ordinary care in rendering medical judgments that affect treatment simply because an HMO has chosen to undertake that duty as a component of a plan that it markets to employers. Stated differently, in providing an exclusive set of remedies for claims arising from ERISA plans, there is no indication that Congress clearly and manifestly intended to create a liability shield for plan administrators by allowing them to take any activity traditionally subject to state regulation and distilling it into a contract term in the plan. *See Hook v. Morrison Milling*, 38 F.3d 776, 783 (CA5 1994) ("ERISA was not enacted to allow employers to control which laws or claims are preempted and those which are not. . . . [W]e find no authority for the proposition that a law or claim is

preempted merely because the employer crafts its ERISA plan in such a way that the plan is inconsistent with that law or claim.").

2. *Metropolitan Life*

Taylor also was a suit by an employee arising out of a denial of disability benefits by the insurer of his employer's benefits plan. 481 U.S., at 60-61. The employee's specific claims against the insurer were breach of the insurance contract for the denial of benefits and an apparent tort claim described by the court of appeals as "wrongful termination of benefits." *Taylor v. General Motors Corp.*, 763 F.2d 216, 217 (CA6 1985), *rev'd sub nom. Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987). Through these claims, the employee sought to recover "money contractually owed Plaintiff, compensation for mental anguish caused by breach of this contract, as well as immediate reimplementation [*sic*] of all benefits and insurance coverages Plaintiff is entitled to." *Metropolitan Life*, 481 U.S., at 61. The employee joined with these claims various tort claims against his employer for retaliatory discharge and failure to promote. *Id.* The employer and insurer removed the case to federal court, asserting that the benefits-related claims against the insurer were preempted by ERISA, and that the district court could exercise pendent jurisdiction over the claims against the employer. *Id.*

Relying on *Pilot Life*, the Court held that the district court did have removal jurisdiction over the employee's suit because the benefits-related claims were so completely preempted by ERISA §502(a) that they were "converted" into federal questions. *See id.*, at 62-67. While reviewing the discussion of the legislative history in *Pilot Life*, the Court also noted that Senator Williams, a sponsor of ERISA, emphasized that "suit[s] to recover benefits denied contrary to the terms of the plan" would be deemed federal questions in the same manner that LMRA §301 preempted actions for violations of labor contracts. *Id.*, at 66. This explicit legislative intent persuaded the Court to overcome its "reluctan[ce] to find that

extraordinary pre-emptive power" that overrides the well-pleaded complaint rule. *Id.*, at 65.

Therefore, the Court held that §502(a) entirely preempted a breach of contract claim to recover plan benefits and, as in *Pilot Life*, a tort claim apparently predicated on a general duty of good faith imposed on contracting parties—*i.e.*, not to terminate contractual benefits "wrongfully." *See Taylor*, 763 F.2d, at 217. For the same reasons that *Pilot Life* is inapposite, *see supra*, Part.II.A.1, *Metropolitan Life* does not control the preemption question in this case.

3. *Ingersoll-Rand*

In *Ingersoll-Rand*, the employee sued his employer for the state-law tort of wrongful discharge, claiming that his employer terminated his employment to avoid making contributions to his ERISA-regulated pension fund. 498 U.S., at 135-36. As in *Pilot Life*, the issue presented was not removal jurisdiction, but whether the employer was entitled to summary judgment based on its defense of ERISA preemption. *See id.*, at 136. The Court initially addressed and determined that the wrongful discharge claim was expressly preempted under ERISA §514(a). *Id.*, at 138-142. In the alternative, however, the Court also examined whether this claim was impliedly preempted because of the complete preemptive force of §502(a)'s civil-enforcement scheme. *Id.*, at 142-45.

The Court began its §502(a) analysis by noting that the employee's wrongful discharge claim "falls squarely within the ambit of ERISA §510." *Id.*, at 142. That section provides in pertinent part:

> "It shall be unlawful for any person to discharge, fine, suspend, expel, discipline, or discriminate against a participant or beneficiary for exercising any right to which he is entitled under the provisions of an employee benefit plan . . . *or for the purpose of interfering with the attainment of*

> *any right to which such participant may become entitled* under the plan . . . ." *Id.*, at 142-43 (quoting 29 U.S.C. §1140).

Thus, §510 prohibited precisely the sort of conduct complained of in the employee's wrongful discharge claim.

The employee in turn had a direct means to enforce §510's prohibition against interfering with the attainment of plan benefits—the enforcement provisions in §502(a). Specifically, the employee had the right under §502(a)(3) to file an action to enjoin violations of §510 or to obtain "other appropriate equitable relief" to redress the §510 violations. *Id.*, at 143 (quoting 29 U.S.C. §1132(a)(3)). "Unquestionably, the Texas cause of action [in *Ingersoll-Rand*] purports to provide a remedy for the violation of a right expressly guaranteed by §510 and exclusively enforced by §502(a)." *Id.*, at 145. For these reasons, the Court held, "[w]hen it is clear or may fairly be assumed that the activities which a State purports to regulate are protected by §510 of ERISA, due regard for the federal enactment requires that state jurisdiction must yield." *Id.* (internal quotations and citation omitted).

By contrast, the right to be free from negligent medical decisions that adversely affect treatment is not guaranteed or even addressed by §510 or any other provision of ERISA. Thus, §502(a)'s remedies to redress ERISA violations are not implicated by Davila's and Calad's suits, and therefore, *Ingersoll-Rand*'s rationale for complete preemption does not apply.

C. Aetna and CIGNA Have Not Otherwise Shown That Congress Clearly and Manifestly Intended to Preempt State Health-Care Liability Claims.

Not only have Aetna and CIGNA failed to demonstrate controlling support in the Court's previous §502(a) complete-preemption decisions, but they have not otherwise shown that Congress clearly and manifestly intended to preempt state health-

care regulation of this sort when HMOs undertake medical decision-making in the course of coverage determinations that affects the quality of patients' treatment.

The language, structure, and legislative history of ERISA are devoid of any evidence that preempting state health-care law was an element of the congressional design. The Court has observed that "nothing in the language of the Act or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Travelers*, 514 U.S., at 661. And, in explaining that the indirect costs of state regulation alone do not constitute an impermissible intrusion into ERISA's exclusive sphere, the Court pointedly noted, "if ERISA were concerned with any state action—*such as medical care quality standards . . .*—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, we could scarcely see the end of ERISA's pre-emptive reach." *Dillingham Constr.*, 519 U.S., at 329 (emphasis added). Neither Aetna nor CIGNA has rebutted this assessment of ERISA's preemptive scope as it relates to health-care regulation.

Instead, Aetna's and CIGNA's principal contention is that, "at bottom," Davila and Calad complain only that they were denied coverage under their respective health plans, notwithstanding the medical judgment attending the coverage decision or its effect on the treatment delivered. *See* Aetna Br., at 26-28; CIGNA Br., at 25-31. But the Court has already rejected this characterization in *Pegram* when it noted that "medical necessity determinations" are in fact "mixed eligibility and treatment decisions." *See* 530 U.S., at 229-30. This more accurate description of "medical necessity" determinations reverberates in the preemption analysis in three ways:

- It removes such determinations from the category of "pure eligibility" decisions that are indisputably preempted by §502(a).

- As the Court noted, it defeats any suggestion that Congress clearly and manifestly intended that ERISA's fiduciary provisions preempt state-law regulation targeting such determinations. *See id.*, at 231 (expressing "doubt that Congress would ever have thought of a mixed eligibility decision as fiduciary in nature"), 232 (noting that "it is at least questionable whether Congress would have had mixed eligibility decisions in mind when it provided that decisions administering a plan were fiduciary in nature").

- Finally, the Court's decision that ERISA's fiduciary provisions did not extend to mixed eligibility decisions was explicitly predicated in part on its recognition that state malpractice law already addressed claims targeting these determinations. *See id.*, at 235-37 (observing that an ERISA fiduciary action covering mixed eligibility decisions would unnecessarily federalize existing state malpractice actions against HMOs).

Aetna's and CIGNA's response to *Pegram* is twofold. First, they suggest that *Pegram*'s analysis should be limited to physician-owned HMOs and not extended to third-party HMOs that contract with a network of treating physicians. *See* Aetna Br., at 29-37; CIGNA Br., at 33-40. But as discussed in Part I, the Court in *Pegram* dispelled any notion that its assessment of mixed eligibility and treatment decisions was so confined. *See supra*, Part I.A.1; *see also Pegram*, 530 U.S., at 228-29. And, although Aetna and CIGNA may not have employed Davila's and Calad's treating physicians, they made "when-and-how" decisions in determining coverage that substantially directed the treatment given, with injurious results. *See supra*, Part I.A.2.

Aetna and CIGNA also attempt to deflect *Pegram* by asserting that the question whether Congress intended mixed eligibility and treatment decisions to be redressed through ERISA fiduciary claims is not dispositive of the preemption analysis. Aetna Br., at 35-37;

CIGNA Br., at 33; *see also* U.S. Br., at 26-27. In other words, while ERISA's remedies for breach of fiduciary duty (§502(a)(2) & (3)) do not redress claims for negligent mixed eligibility/treatment decisions under *Pegram*, state-law claims directed at the same wrongful conduct nonetheless remain completely preempted by as a result of §502(a)'s exclusive scheme. The result is to consign such claims to a "no-man's land" in which neither a federal or state remedy is available.

This conception of preemption necessarily fails because it is unsupported by any clear and manifest congressional purpose. Aetna and CIGNA have not directed the Court to any evidence that, in providing an exclusive remedial scheme to redress improper plan administration, Congress also clearly intended:

(1) to create a safe harbor from state health-care standards and substantive liability for HMOs that make negligent medical-necessity determinations adversely affecting the quality of treatment, so long as the negligence occurs in the course of a coverage decision; and

(2) at the same time, to exclude medical-necessity determinations from ERISA's fiduciary obligations and otherwise provide no relief for personal injuries proximately caused by negligent determinations.

In the absence of any positive indications of such intent, the Court has been rightly reluctant to interpret ERISA to effect preemption under these circumstances. *See Dillingham Constr.*, 519 U.S., at 330 (noting that "pre-emption of traditionally state-regulated substantive law in those areas where ERISA has nothing to say would be unsettling") (internal quotation and citation omitted).

For these reasons, substantial doubts have been raised as to whether Congress intended §502(a)'s preemptive effect to reach state-law malpractice claims arising from HMO's negligent medical-necessity determinations. For example, Judge Becker lamented the

"ERISA preemption nightmare" occasioned by the analysis urged by Aetna and CIGNA here. *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 464 (CA3 2003) (Becker, J., concurring). Under that interpretation, "ERISA *de facto* places the HMO in control of the treatment a participant receives, yet it preempts any state-law medical malpractice claim against that HMO and provides that the participant can recover no compensatory, punitive, or wrongful death damages regardless of its malfeasance." *Id.* Addressing whether this regime squared with congressional intent, Judge Becker commented:

> "[I]t is unlikely that Congress intentionally created this so-called, 'regulatory vacuum,' in which it displaced state-law regulation of welfare benefit plans while providing no federal substitute. The more likely explanation is that Congress merely intended to create minimum safeguards to protect the financial integrity of welfare benefit plans while stopping short of federalizing the entire remedial regime, especially in light of what was a workable state-law remedial system." *Id.*, at 467.

If it is "unlikely" that Congress intended the "regulatory vacuum" generated by Aetna's and CIGNA's analysis, then there is no "clear and manifest purpose" to support complete preemption in this area. *See Pegram*, 530 U.S., at 237.

Likewise, the Second Circuit has observed that, in devising §502(a)'s civil-enforcement scheme, Congress did not anticipate the widespread use of prospective utilization review to make benefit-eligibility determinations at the point of treatment. *Cicio v. Does*, 321 F.3d 83, 98-99 (CA2 2003). "Prospective utilization review blurs boundaries between the traditionally distinct sphere of professional dominance and autonomy of the medical profession on the one hand, and the managerial domain on the other. As such, *it represents a development apparently unforeseen at the time of ERISA's enactment*." *Id.*, at 98 (internal citations and quotations

omitted) (emphasis added). Thus, in selecting remedies to redress improper plan administration, there is no indication that Congress contemplated that plan administrators would be making pre-treatment medical judgments—traditionally subject to state-law standards—with "dispositive consequences for the course of treatment that a patient ultimately follows." *See id.*, at 98-99. Again, in the absence of "clear and manifest" congressional intent in this regard, there is no complete preemption. *See Pegram*, 530 U.S., at 237.

CONCLUSION

The *Amici* States urge the Court to affirm the judgment of the Fifth Circuit Court of Appeals.

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